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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,191

03/10/2005

Leif Kongerslev

KONGERSLEV2

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EXAMINER

MONDESI, ROBERT B

ART UNIT

PAPER NUMBER

1652

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

12/19/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,191	KONGERSLEV ET AL.	
	Examiner	Art Unit	
	Robert B. Mondesi	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-7, 9, 11, 13, 15, 17, 18, 20-33, 37, 39-42 and 49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1, 3-7, 9, 11, 13, 15, 17-18, 20-33, 37, 39-42 and 49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Status of the Claims

Claims 2, 8, 10, 12, 14, 16, 19, 34-36, 38, 43-48 and 51-53 have been canceled.

Claims 1, 3-7, 9, 11, 13, 15, 17-18, 20-33, 37, 39-42 and 49 are presently pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 3-7, 9, 11, 13, 15, 17-18 and 20-30, drawn to a fusion protein comprising first protein derived from a lectin-complement pathway and a second protein capable of associating with one or more carbohydrates.

Group II, claim(s) 31, drawn to an isolated nucleic acid encoding a fusion protein comprising first protein derived from a lectin-complement pathway and a second protein capable of associating with one or more carbohydrates, a vector comprising the said nucleic acid and a host cell comprising the said vector.

Group III, claim(s) 37, 39-42, drawn to a method of prevention and or treatment of an infection comprising administering a fusion protein comprising first protein derived from a lectin-complement pathway and a second protein capable of associating with one or more carbohydrates.

Group IV, claim(s) 49, drawn to a pharmaceutically acceptable composition for the treatment or prevention of a clinical condition in an individual comprising a fusion protein comprising first protein derived from a lectin-complement pathway and a second protein capable of associating with one or more carbohydrates.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: IV.

The technical feature linking Groups I-IV appears to be that they all relate to a fusion protein comprising first protein derived from a lectin-complement pathway and a second protein capable of associating with one or more carbohydrates.

However, Matsushita et al., 2002 (cited in the IDS filed October 13, 2005) disclose a fusion protein comprising first protein derived from a lectin-complement pathway and a second protein capable of associating with one or more carbohydrates; therefore the technical feature linking the inventions of Groups I-IV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, Groups I-IV are not so linked by the same or a corresponding special technical feature as to form a single inventive concept.

Restriction Requirement Applicable to all Groups

Furthermore, the presence of multiple polypeptide sequences and polynucleotide sequences, each with a different SEQ ID NO: allows for a variety of patentably distinct products. Depending on the sequence of each polypeptide and polynucleotide, the characteristics of the resulting molecule will vary in regards to structure and function. Each one of these polypeptides is capable of eliciting a specific immune response and can be used to produce a specific antibody; also each one of the mentioned polynucleotides is capable of hybridizing to different probes and is capable of encoding a characteristically different peptide in regards to structure and activity. Therefore these polypeptides and polynucleotides are patentably distinct absent factual evidence to the contrary. Rejoinder of all or a specified subset of the sequences is possible if Applicants

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provide a single and specific representative subsequence found in all or a specified subset of the sequences for search, and state that all or a specified subset of the sequences are not patentably distinct. Applicants are informed that if their specified sequence is found that all or a specified subset of sequences are obvious over that prior art sequence.

Applicant is required under 35 U.S.C. 121 to elect a single SEQ ID NO: for prosecution on the merits. The applicant should be aware that selection of a single SEQ ID NO: represents a response to a restriction requirement of a patentably distinct product, not an election of species.

Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

MASP-1, MASP-2 and MASP-3 (claim 6); L-ficolin, H-ficolin and M-ficolin (claim 8); MBL (mannose-binding lectin), SP-A (lung surfactant protein A), SP-D (lung surfactant protein D), BK (or BC, bovine conglutinin) and CL-43 (collectin-43) (claim 17); CRD domain of MBL, neck region of MBL, collagen-like domain of MBL, CRD domain of MBL, (claims 21-24).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

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subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 6: MASP-1, MASP-2 and MASP-3.

Claim 8: L-ficolin, H-ficolin and M-ficolin.

Claim 17: MBL (mannose-binding lectin), SP-A (lung surfactant protein A), SP-D (lung surfactant protein D), BK (or BC, bovine conglutinin) and CL-43 (collectin-43).

Claims 21-24: CRD domain of MBL, neck region of MBL, collagen-like domain of MBL, CRD domain of MBL.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each one of the peptides above has a different amino acid sequence and elicits a specific immune response and can be used in an independently distinct assay.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

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all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert B Mondesi
Examiner
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12-14-06